No. 80-2182

Office - Supreme Court, U.S.
FILED
NOV 25 1981
ALEXANDER L. STEVAS,
CLERK

IN THE

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC. and
PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

BRIEF ON THE MERITS OF PETITIONER PREMO PHARMACEUTICAL LABORATORIES, INC.

PETER T. COBBIN
KIRSCHSTEIN, KIRSCHSTEIN,
OTTINGER & COBBIN, P.C.
Attorneys for Petitioner
Premo Pharmaceutical Laboratories, Inc.
666 Fifth Avenue
New York, New York 10103
(212) 581-8770

Of Counsel:
DAVID B. KIRSCHSTEIN
MARTIN W. SCHIFFMILLER

Questions Presented

I. Whether the sale of a product with an appearance that simulates the unpatented and uncopyrighted appearance, principally the surface coloration, of another manufacturer's product which is identified by a registered word trademark can be enjoined on the ground that such sale contributes to the infringement of said trademark by purchasers and thus violates Section 32 of the Lanham Act, 15 U.S.C. §1114.

II. Whether the sale of a product as described in Question I can be enjoined on the ground that such sale constitutes or contributes to passing off and hence false designations of origin in violation of Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a).

III. Whether the sale of a product as described in Question I can be enjoined where the appearance of the product which has been copied is the one to which consumers became accustomed during the period when that product was protected by a patent and hence no other manufacturer could sell such a product.

IV. Whether the sale of a product as described in Question I to licensed professionals (pharmacists) can be enjoined on the ground that a small number of those professionals utilize the product to commit acts which leave them liable to criminal and/or civil penalties, including loss of license, even though the seller of the product did not counsel, suggest or induce such acts.

Statement Pursuant to Supreme Court Rules 21 and 28.1

The other parties to the proceeding in the court whose judgment is sought to be reviewed were appellees Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.

The parent company of petitioner Inwood Laboratories, Inc. is Forest Laboratories, Inc. Petitioner Premo Pharmaceutical Laboratories, Inc. is affiliated with Federal Pharmacal Co.

TABLE OF CONTENTS

	PAGE
Questions Presented	I
Statement Pursuant to Supreme Court Rules 21 and 28.1	II
Opinions Below	1
Jurisdiction	2
Statutes and Administrative Rules Involved	2
Statement of the Case	2
Summary of the Argument	2
Point I—Copying of the Unpatented and Uncopyrighted Appearance of a Product Cannot Be Barred on the Ground that Such Copying Contributes to the Infringement of a Registered Word Trademark by Purchasers	5
Point II—Copying by the Appellants of the Appearance of the Respondent's Product Cannot Be Enjoined on the Ground that Such Copying Constitutes or Contributes to a Violation of Section 43(a) of the Lanham Act	20
Point III—Even if the Appearance of Respondent's Blue Capsules Were Associated by the Public with Respondent, Petitioners Could Not Be Enjoined from Copying that Appearance Because the Public Recognition Thereof Was Acquired During the Period of Respondent's Patent Monopoly	27
Point IV—Copying of the Appearance of Respondent's Products by Petitioners Cannot Be Enjoined on the Basis of Illegal Acts Committed by a Small Number of Licensed Professionals Who Utilize Those Products	29
Conclusion	34

TABLE OF AUTHORITIES

PAGE

Cases:

Bates v. State Bar of Arizona, 433 U.S. 350 (1977) 4, 30, 32, 33

Coca-Cola Co. v. Snow Crest Beverages, 64 F. Supp. 980 (D. Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir.), *cert. denied*, 332 U.S. 809 (1947) 7

Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964) 3, 8, 9, 10, 11, 19, 21, 23

Corning Glass Works v. Jeannette Glass Co., 308 F. Supp. 1321 (S.D.N.Y.), *aff'd*, 432 F.2d 784 (2d Cir. 1970) 16

E.R. Squibb & Sons, Inc. v. Premo Pharmaceutical Laboratories, Inc., 195 U.S.P.Q. 545 (S.D.N.Y. 1977) 12, 13, 14

Ives Laboratories, Inc. v. Darby Drug Co., 455 F. Supp. 939 (E.D.N.Y. 1978) 1, 6, 13, 22

Ives Laboratories, Inc. v. Darby Drug Co., 601 F.2d 631 (2d Cir. 1979) 1, 6, 8, 19, 21, 22, 24, 32

Ives Laboratories, Inc. v. Darby Drug Co., 488 F. Supp. 394 (E.D.N.Y. 1980) 2, 6, 7, 17, 22, 25, 29

Ives Laboratories, Inc. v. Darby Drug Co., 638 F.2d 538 (2d Cir. 1981) ..... *passim*

Kellogg Co. v. National Biscuit Co., 305 U.S. 111 (1938) 4, 27, 28, 29

Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc., 194 U.S.P.Q. 157 (D.N.J. 1977), *aff'd on procedural grounds*, 579 F.2d 386 (3d Cir. 1977) 12, 15

Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960) 24

PAGE

Saxony Products, Inc. v. Guerlain, Inc., 513 F.2d 716 (9th Cir. 1975) 19
Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 1964) 3, 8, 9, 10, 11, 19, 21, 23, 29
Smith v. Chanel, Inc., 402 F.2d 562 (9th Cir. 1968) 17, 18
Smith Kline & French Laboratories v. Broder, 125 U.S.P.Q. 299 (S.D. Tex. 1959) 12, 14, 15
Smith, Kline & French Laboratories v. Clark & Clark, 157 F.2d 725 (3d Cir.), *cert. denied*, 329 U.S. 796 (1946) 24
Societe Comptoir de L'Indus., etc. v. Alexander's Dep't Stores, 299 F.2d 33 (2d Cir. 1962) 18, 19
Stewart Paint Mfg. Co. v. United Hardware Distributing Co., 253 F.2d 568 (8th Cir. 1958) 16
Stix Products, Inc. v. United Merchants & Mfrs., Inc., 295 F. Supp. 479 (S.D.N.Y. 1968) 16

Upjohn Co. v. Schwartz, 246 F.2d 254 (2d Cir. 1957) 12, 13, 16, 17, 24, 25

Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976) 4, 30, 31, 32, 33

William R. Warner & Co. v. Eli Lilly & Co., 265 U.S. 526 (1924) 23, 24, 25

Statutes:

Lanham Act, Section 32, 15 U.S.C. § 1114 ..... 2, 6, 10, 11, 12, 13, 20, 22, 29, 33
Lanham Act, Section 43(a), 15 U.S.C. § 1125(a) 2, 3, 15, 17, 19, 20, 21, 22, 25, 26
28 U.S.C. § 1254(1) 2

No. 80-2182

IN THE

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC. and
PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

BRIEF ON THE MERITS OF PETITIONER PREMO PHARMACEUTICAL LABORATORIES, INC.

Opinions Below

The first opinion of the district court denying respondent's request for preliminary injunctive relief on its primary claims is officially reported at 455 F. Supp. 939 (E.D.N.Y. 1978) (Pet. App. 1a).[1] The Court of Appeals decision affirming the district court's denial of preliminary injunctive relief is officially reported at 601 F.2d 631 (2d Cir. 1979) (Pet. App. 28a).

1. Citations in the form "Pet. App. ——a" refer to pages in the Appendices to the Petition for Certiorari filed herein.

The opinion of the district court after trial, dismissing respondent's complaint, is officially reported at 488 F. Supp. 394 (E.D.N.Y. 1980) (Pet. App. 54a). The opinion of the Court of Appeals which is at issue herein, reversing the district court decision on the merits, is officially reported at 638 F.2d 538 (2d Cir. 1981) (Pet. App. 71a).

Jurisdiction

The judgment of the United States Court of Appeals for the Second Circuit, sought to be reviewed herein, was entered on January 8, 1981. Petitioners' subsequent request for a rehearing was denied on February 25, 1981 without opinion. The jurisdiction of this Court is invoked under 28 U.S.C. Section 1254(1).

Statutes and Administrative Rules Involved

The statutory provisions involved herein are Sections 32 and 43(a) of the Lanham Act, 15 U.S.C. §§1114 and 1125(a) (Pet. App. 107a-111a).

Statement of the Case

Petitioner Premo Pharmaceutical Laboratories, Inc. ("Premo") adopts and incorporates by reference herein the Statement of the Case set forth in the Brief on the Merits of Petitioner Inwood Laboratories, Inc.

Summary of the Argument

The relief granted by the Second Circuit under Section 32 of the Lanham Act against copying of the appearance of respondent's products directly conflicts with the policy

against free and unrestricted copying of the unpatented and uncopyrighted appearance of articles of manufacture enunciated by this Court in *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964) and *Compco Corp.* v. *Day-Brite Lighting Co.*, 376 U.S. 234 (1964). Moreover, there is no previous case where a court enjoined the copying of such an unpatented and uncopyrighted appearance on the ground of contributory trademark infringement. Instead, where the courts have found that encouragement or inducement of such infringement has taken place in connection with a look-alike product, the unfair acts of inducing, encouraging or contributing to the infringement were enjoined, and not the copying of the product appearance.

Petitioners' sale of drug products imitating the appearance of respondent's CYCLOSPASMOL product can also not be enjoined on the ground that such copying constitutes or contributes to passing off by pharmacies and hence "false designations of origin" in violation of Section 43(a) of the Lanham Act. Respondent established neither of the requisite elements of a claim under §43(a) arising out of the simulation of a product, i.e., that the appearance of the product is non-functional and has acquired secondary meaning. On the contrary, petitioners introduced substantial evidence that was found credible by the trial court demonstrating the functional nature of the appearance of respondent's products and the valid policy considerations which motivated petitioners to copy that appearance.

One of the two products of respondent at issue herein, the pale blue 200 mg. CYCLOSPASMOL capsule, was sold in that very appearance for many years during the time when respondent owned a patent on cyclandelate and no

other manufacturer could sell a cyclandelate product in the United States. Thus, any significance in terms of source identification that the appearance of the pale blue capsules may have to consumers was developed during the term of respondent's patent monopoly. Enjoining petitioners from copying the appearance of that product of respondent after the patent owned by respondent on the drug itself expired is prohibited by the holding of this Court in *Kellogg Co.* v. *National Biscuit Co., Inc.*, 305 U.S. 111 (1938), which viewed such a prohibition as in the nature of an extension of the patent monopoly beyond its legal term.

The Second Circuit relied on evidence that a small number of professionals, specifically pharmacists, either legally substituted petitioners' generic products for that of respondent, or mislabeled prescription bottles containing the generic products as respondent's CYCLOSPASMOL product, in support of its ruling that petitioners had contributed to the infringement of the CYCLOSPASMOL trademark and thus could be prohibited from selling a look-alike product even to the vast majority of pharmacies throughout the country who do not engage in such illegal and unscrupulous practices. This Court, however, has held in cases such as *Bates* v. *State Bar of Arizona*, 433 U.S. 350 (1977), and *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) that improper acts committed by individual professional practitioners such as pharmacists and lawyers do not provide a basis for a blanket prohibition against practices that are essentially in the public interest. Petitioners established at trial that the sale of look-alike generic equivalents of more expensive branded drugs is indeed in the public interest and the Court

of Appeals should not have enjoined such a practice merely because of the improper actions of a few pharmacists who purchased petitioners' products. This is particularly the case when pharmacists who commit those improper acts are subject to criminal and civil penalties, including loss of license.

POINT I

Copying of the Unpatented and Uncopyrighted Appearance of a Product Cannot Be Barred on the Ground that Such Copying Contributes to the Infringement of a Registered Word Trademark by Purchasers.

The Second Circuit, scarcely paying lip service to the detailed findings of fact made by the district court after an extensive trial, held that the evidence in this case established that petitioners could reasonably anticipate that their generic cyclandelate products, sold in capsules of identical color, size and shape to the respondent's branded cyclandelate products, would be sold by a substantial number of druggists under respondent's registered trademark CYCLOSPASMOL (Pet. App. 82a). The Second Circuit also cited the petitioners' use of advertising comparing the prices of CYCLOSPASMOL brand cyclandelate and petitioners' generic cyclandelate products as an additional factor contributing to the "likelihood" that pharmacists would either illegally substitute the generic products when a prescription required CYCLOSPASMOL capsules or simply mislabel the generic product as CYCLOSPASMOL in instances where substitution of the generic was permitted (*id.*). Accordingly, the court held (Pet. App. 86a) that petitioners should be enjoined from selling their look-alike

cyclandelate products on the ground that the sale of such products constitutes contributory trademark infringment under Section 32 of the Lanham Act, 15 U.S.C. §1114.

Petitioners submit that even if the situation were as stated by the Second Circuit, the fact that pharmacists were using petitioners' look-alike products to commit acts of trademark infringement cannot serve as a basis for enjoining the copying of the appearance (principally the surface coloration) of the respondent's products, which appearance is neither patented nor copyrighted, and this is so regardless of whether or not appellants can be said to have contributed to or suggested such trademark infringement.

The applicable law relating to contributory trademark infringement under Section 32 of the Lanham Act was extensively discussed by the Second Circuit in *Ives II*[2] (Pet. App. 34a-36a). The court held that a manufacturer or wholesaler would be liable under Section 32 of the Lanham Act,

> "if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and

2. For the sake of convenient reference, the decisions below will henceforth be referred to as follows:

Ives I—The district court decision denying a preliminary injunction, reported at 455 F.Supp. 939 (E.D.N.Y. 1978).

Ives II—The Second Circuit decision affirming the denial of a preliminary injunction, reported at 601 F.2d 631 (2d Cir. 1979).

Ives III—The district court decision after trial, reported at 488 F.Supp. 394 (E.D.N.Y. 1980).

Ives IV—The Second Circuit opinion reversing the district court's decision on the merits, reported at 638 F.2d 538 (2d Cir. 1981).

> apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described."

(Pet. App. 35a). The court cited with approval the criteria for a finding of contributory trademark infringement set forth by Judge Wyzanski in *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F.Supp. 980, 989 (D. Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir. 1947), *cert. denied*, 332 U.S. 809 (1947). In that case, Judge Wyzanski held that before a party can be liable as a contributory infringer, he must have knowledge that the persons to whom he supplies the instrument by which the latter commit the infringement will or can reasonably be expected to commit the infringement with the instrument supplied. "The test is whether wrongdoing by the purchaser 'might well have been anticipated by the defendant.'" *Id.* (citation omitted).

Applying the Second Circuit's and Judge Wyzanski's definition of the tort of contributory trademark infringement, the trial court in this case found that:

> ". . . defendants did not suggest, even by implication, that pharmacists fill bottles with the generic drug cyclandelate and apply the trademark Cyclospasmol. Nor did Ives show that defendants continued to sell the generic drug to pharmacists who defendants knew or had reason to know were engaging in such a practice. 601 F. 2d at 636."

(Pet. App. 59a).

Without even applying the "clearly erroneous" test to these findings of fact by the trial court, the Court of Appeals in *Ives IV* nevertheless reversed the district court on

the contributory trademark infringement issue, finding that the petitioners "could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally for Ives' trademarked CYCLOSPASMOL or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage." (Pet App. 82a). The court further held that petitioners' sale of their products under these circumstances amounted to a suggestion, at least by implication, that the druggists engage in such misconduct (Pet. App. 82a-83a).[3]

Aside from the incorrect and improper reversal by the Court of Appeals of the findings of fact and conclusions of law made by the district court in following the guidelines set down in *Ives II*,[4] it is submitted by petitioner Premo that under the strong public policy enunciated by this Court in cases such as *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964) and *Compco Corp.* v. *Day-Brite Lighting Co.*, 376 U.S. 234 (1964) favoring copying of the unpatented and uncopyrighted appearance of articles of manufacture in order to promote free and open competition, the sale by petitioners herein of look-alike generic cyclandelate products could not be enjoined even if they were indeed

3. It is interesting to note that the Second Circuit in *Ives IV* thus consolidated the two alternative criteria for a finding of contributory trademark infringement set forth in *Ives II* into one criterion. Apparently, according to the *Ives IV* court, once it is found that a seller could reasonably anticipate that the purchaser would use the product to infringe, the seller is viewed, without having committed any additional act of inducement, as having suggested that the purchaser engage in this improper conduct.

4. See Judge Mulligan's dissenting opinion in *Ives IV* on this point (Pet. App. 90a-91a).

guilty of suggesting, inducing or contributing to trademark infringement by retail pharmacists.

The *Sears* and *Compco* cases were, technically, decided on grounds of the supremacy of federal patent and copyright law over state unfair competition law, and this Court held that a state could not enjoin, under the guise of unfair competition, the copying by a competitor of the appearance of an article which was not patented or copyrighted (either because not statutorily subject to patent or copyright, because no such protection was secured by the manufacturer or originator thereof or because any patent or copyright protection had expired). The policy enunciated in those cases strongly favoring the unrestricted copying of unpatented and uncopyrighted articles is applicable to the facts of the case at bar.

In *Sears,* for example, the Court rejected the argument that the manufacture by the defendant Sears of an article which looked exactly like Stiffel's unpatented lamp was likely to cause confusion to consumers and thus should be enjoined. Acknowledging that there could be confusion between two such nearly identical articles, the Court nevertheless stated:

> "But mere inability of the public to tell two identical articles apart is not enough to support an injunction against copying or an award of damages for copying that which the federal patent laws permit to be copied."

376 U.S. at 232. The point was even more forcefully made in *Compco,* wherein the Court expressed the following views regarding the copying of an unpatentable article:

> "Under the federal patent laws it is, therefore, in the public domain and can be copied in every detail by who-

> ever pleases. It is true that the trial court found that the configuration of Day-Brite's fixture identified Day-Brite to the trade because the arrangement of the ribbing had, like a trademark, acquired a 'secondary meaning' by which that particular design was associated with Day-Brite. *But if the design is not entitled to a design patent or other federal statutory protection, then it can be copied at will.*"

376 U.S. at 237-38 (emphasis supplied).

The Court of Appeals in *Ives IV* purported to hold only that the copying of the appearance of respondent's capsules, which appearance is not and has never been the subject of patent or copyright, should be enjoined under Section 32 of the Lanham Act because the sale of such look-alike products contributed to infringement of the trademark CYCLOSPASMOL associated with the respondent's products. The Second Circuit did not rule that such an injunction would lie under state unfair competition law, and therefore no issue of conflict with federal patent policy is squarely presented.[5] But it is submitted that under the doctrine set forth in the *Sears* and *Compco* cases, only the constitutionally mandated and statutorily created limited exceptions to the general rule of free and open competition, *viz.*, patents and copyrights, can provide the basis for an injunction against copying the appearance of a product. Such copying cannot be barred (as was held in *Ives IV*) merely because of the possibility that it assists or encourages purchasers to independently commit unfair compet-

5. The appearances of respondent's products at issue herein have neither been federally registered nor are they registrable as trademarks under the provisions of the Lanham Act. In fact, respondent never made any direct claim and there is no finding by any court below that the appearances of respondent's products are themselves trademarks in any sense.

itive acts such as infringement of a trademark applied to the article.

At the end of the majority opinion in the *Sears* case, this Court acknowledged that states could protect businesses in the use of their trademarks, labels and trade dress in order to prevent passing off of goods or deception of purchasers. But the Court emphasized that copying of the article itself could not be enjoined by a state nor could damages be awarded for such copying. *Id.* at 232-33. The dictum in *Sears* that a manufacturer could be enjoined (whether under state or federal law) from misleading purchasers as to the source of a product does not support the Second Circuit's ruling in this case that petitioners, who never deceived or confused anyone as to the source of their products, could be enjoined from copying the appearance of respondent's product merely because a small number of retail pharmacists allegedly utilized the look-alike products to commit unlawful acts. This is particularly the case because petitioners always took affirmative steps to ensure that their customers, who are drug wholesalers, distributors and retailers, were fully aware of the source of petitioners' products.[6]

The Second Circuit cited no authority for the proposition that the type of copying described in *Sears* and *Compco* as permissible under virtually all circumstances could be enjoined because purchasers of the look-alike products allegedly utilized the same to violate Section 32 of the Lan-

6. Petitioners sell their products in bottles which clearly identify the source of the product. Although consumers do not see the labeled bottles, it can in no way be said that petitioners pass off their products on *their* customers or deceive their customers as to the source of the goods.

ham Act. The only cases cited by the *Ives IV* court[7] which allegedly enjoined "similar activity" as "enabling druggists to defraud by palming off" (Pet. App. 83a) are cases which did not deal with §32 at all and are clearly distinguishable either on their facts or because the relief granted fell far short of enjoining copying of appearance.

In *Upjohn* v. *Schwartz, supra,* it was found that the defendant and his agents had actively counseled customers to illegally substitute his prescription drug products for the plaintiff's. The Court of Appeals held that the manufacturer's suggestion to the druggists that the products could be substituted for a competitor's product was itself a type of passing off and unfair competition. Even so, defendant was not enjoined from simulating the appearance of the drug products because the court held (246 F.2d at 256) that the plaintiff had no monopoly "on a capsule or a tablet of a particular size, shape or color." The defendant was enjoined only from representing or suggesting to anyone that his products could be substituted for pharmaceutical products of other manufacturers having a similar appearance when a prescription specifically called for the products of the other manufacturers.[8] The defendant was also re-

7. *Upjohn Co.* v. *Schwartz,* 246 F.2d 254 (2d Cir. 1957); *Merrell-National Laboratories, Inc.* v. *Zenith Laboratories, Inc.,* 194 U.S.P.Q. 157 (D.N.J. 1977), *aff'd on procedural grounds,* 579 F.2d 386 (3d Cir. 1978); *E.R. Squibb & Sons, Inc.* v. *Premo Pharmaceutical Labs., Inc.,* 195 U.S.P.Q. 545 (S.D.N.Y. 1977); *Smith Kline & French Laboratories* v. *Broder,* 125 U.S.P.Q. 299 (S.D. Tex. 1959).

8. It is significant that at the time of the *Upjohn* decision and several other cases involving the passing off or illegal substitution of one pharmaceutical product for another, there were no state generic substitution laws which permitted the substitution of a generic version of a branded medication prescribed by the physician. Before these laws were enacted, the pharmacist had to fill a prescription as

(footnote continued on next page)

quired to attach to his bottles or containers a notice that the contents were not to be sold or dispensed as the product of the plaintiff. Imitation of appearance was not prohibited by the *Upjohn* court; only the unlawful express suggestion of substitution was enjoined. Furthermore, the court did not deal with the issue of contributory trademark infringement or Section 32 of the Lanham Act and certainly did not hold that copying of the appearance of the products could be enjoined because it might in itself induce such infringement.

E.R. Squibb & Sons, Inc. v. *Premo Pharmaceutical Labs., Inc., supra,* involved the copying of the *package* dress of one of the plaintiff's products by the defendant. The defendant was ultimately enjoined from copying the appearance of plaintiff's package because it had acquired a secondary meaning, i.e., was recognized by consumers as identifying the product of a particular manufacturer whom they relied on; thus, the sale of a similar product in a colorably similar trade dress was likely to cause confusion of consumers. There was no issue of imitation of the appearance of the product itself or of trademark infringement in that

---

it was written and if, as most physicians were wont to do, the prescription was written for a branded drug product, no other product could be legally substituted therefor. Presently, however, most states have enacted laws which permit the substitution of generic equivalents (see, e.g., the discussion of the New York generic drug substitution law in the district court preliminary injunction opinion (Pet. App. 8a)), usually on the condition that the physician consent to the substitution of a generic equivalent, and thus petitioners committed no impropriety in pointing out to their customers that their product was a generic equivalent to respondent's CYCLOSPASMOL. In fact, as Judge Mulligan observed in his opinion dissenting from the holding of the Second Circuit in this case (Pet. App. 90a, n.4) "it would seem that juxtaposition of the generic and brand name drug [in advertising and promoting generic products] would be imperative for generic manufacturers to compete effectively."

case, either direct or contributory, nor was the defendant enjoined from copying the appearance of the product that was contained in the package. *Squibb*, therefore, has no bearing on the issues presented in this case and decided by the Second Circuit.

In *Smith Kline & French Laboratories* v. *Broder*, *supra*, cited by the *Ives IV* court, the defendant, who had imitated the appearance of the plaintiff's pharmaceutical products and had pointed out the equivalence of the parties' respective products in advertising, using the plaintiff's trademarks in that connection, was found guilty of, *inter alia*, contributory trademark infringement. A very important fact which distinguishes the *Broder* case from the case at bar is that in 1959, when *Broder* was decided, generic drug substitution for a brand name drug was outlawed in virtually every state, including Texas (the law of which was applied in *Broder*). As the district court in that case stated:

> "Substitution by retail druggists of another drug, or the product of another manufacturer, than that called for by the physician's prescription, is an unethical practice in the drug business, and is criminal in this State, as well as many others. It is, however, practiced in many instances, there being a financial inducement thereto, in that the imitative drug usually sells for a fraction of the price which the genuine and well advertised product commands."

125 U.S.P.Q. at 302.

Today, as discussed previously,[9] most states, including the State of New York, permit and even encourage the substitution of generic equivalents for branded drugs as

9. See footnote 8, *supra*.

long as the physician indicates on his prescription that he consents to that substitution. Thus, whereas the comparative advertising and use of the plaintiff's trademarks in the *Broder* case could have had no legitimate purpose, the petitioners herein merely exercised their right to use truthful comparative advertising to promote the legitimate ends of generic drug substitution. In fact, as Judge Mulligan noted in his dissent in *Ives IV*, "it would seem that juxtaposition of the generic and brand name drug [in advertising literature] would be imperative for generic manufacturers to compete effectively" (Pet. App. 90a, n.4).

Even *Merrell-National Laboratories, Inc.* v. *Zenith Laboratories, Inc., supra*, wherein the district court enjoined the sale of look-alike prescription drug products, is of no precedential value for the Second Circuit decision in the present case because it was decided under §43(a) of the Lanham Act and the New Jersey unfair competition law.[10] No issue of contributory trademark infringement was raised or decided in that case.

All cases which preceded *Ives IV*, and which were discussed by the Second Circuit, relating to the sale of look-alike drug products (or drug products in infringing packages) are distinguishable from the case at bar in very substantive, and not merely formalistic, respects. In each of the cases discussed above and all other related cases, the courts either held that the appearance of the product or packaging itself had acquired secondary meaning and that the copying thereof therefore constituted passing off, or merely enjoined the *ancillary* unfair practices, such as the

10. The applicability of §43(a) to the present case will be discussed in greater detail below (see pp. 20a-26a, *infra*).

counseling of illegal substitution, without disturbing the defendant's right to sell a product substantially identical in appearance to that of the plaintiff. In no case did a court enjoin a party from copying the appearance of a drug product on the ground that such copying might somehow encourage or contribute to infringement of the brand name associated with the product.[11]

It should be noted, in addition, that petitioners herein at no time committed unfair and predatory practices of the type perpetrated by the defendant in *Upjohn*. The only practice of the petitioners which the Second Circuit in *Ives IV* could point to as allegedly improper, beyond the mere copying of appearance, was the use of catalogs which described the appearance of the generic cyclandelate products and listed the price of those products in comparison with the price of CYCLOSPASMOL, utilizing the respondent's registered trademark in making that comparison. The use of these catalogs by the petitioners, according

11. Other cases where courts held the defendants guilty of contributory infringement involved factual situations quite different from that in the case at bar. For example, *Corning Glass Works* v. *Jeannette Glass Co.*, 308 F.Supp. 1321 (S.D.N.Y.), *aff'd*, 432 F.2d 784 (2d Cir. 1970) dealt with the simulation by the defendants of a distinctive ornamental feature of the plaintiff's ovenware which had acquired great secondary meaning among consumers, and the use by defendant of an infringing trademark for its products. In *Stix Products, Inc.* v. *United Merchants & Mfrs., Inc.*, 295 F.Supp. 479 (S.D.N.Y. 1968), distinguished by the district court in *Ives I* (Pet. App. 12a-13a), the defendant manufacturer originated and actively engaged in a scheme to facilitate the palming off by retailers of its products as those of the plaintiff. In *Stewart Paint Mfg. Co.* v. *United Hardware Distributing Co.*, 253 F.2d 568 (8th Cir. 1958), the defendant, a wholesaler who had once purchased paint from the plaintiff under the latter's trademark, terminated the contract and began to use that trademark, as well as other distinctive features of the plaintiff's product, in sales of paint purchased from another manufacturer.

No evidence of any such acts by petitioners was introduced in this case.

to the court, created an even greater likelihood that druggists would infringe the CYCLOSPASMOL trademark by applying it to prescription bottles containing the generic products (Pet. App. 82a).

Even if the use by petitioners of catalogs of the type described by the Second Circuit was improper, the Court of Appeals should not have mandated relief against copying the unprotectable appearance of respondent's products, but, instead, as the same court did in *Upjohn*, should have merely enjoined the alleged unfair practices related to the catalogs.

In reality, the Court of Appeals could not even have properly held that petitioners' advertising practices were enjoinable. Petitioners' products are therapeutically equivalent to respondent's CYCLOSPASMOL brand cyclandelate, as found by the district court (Pet. App. 58a) and not challenged by the Court of Appeals (Pet. App. 75a). Thus, under established law, petitioners can legitimately represent that equivalency in their advertising, even though making use of respondent's registered trademark to compare the products in all respects, whether as to appearance, price, or quality. Several cases decided under Section 43 (a) of the Lanham Act emphasize the point that if a party has a right to copy something which is in the public domain, he has the right to tell the public that his product is a copy of, and equivalent to, the well-known brand and use the competitor's trademark in making that legitimate comparison.

In *Smith* v. *Chanel, Inc.*, 402 F.2d 562, 567-68 (9th Cir. 1968), it was alleged that Smith violated §43(a) by ad-

vertising his perfume products as being duplicates of Chanel's famous "No. 5" and other perfumes. The court refused to grant relief, stating, *inter alia*:

> "Since appellees' perfume was unpatented, appellants had a right to copy it, as appellees concede. There was a strong public interest in their doing so, '[f]or imitation is the life blood of competition. It is the unimpeded availability of substantially equivalent units that permits the normal operation of supply and demand to yield the fair price society must pay for a given commodity.' American Safety Table Co. v. Schreiber, 269 F.2d 255, 272 (2d Cir. 1959). *But this public benefit might be lost if appellants could not tell potential purchasers that appellants' product was the equivalent of appellees' product. 'A competitor's chief weapon is his ability to represent his product as being equivalent and cheaper* * * *.'* Alexander, Honesty and Competition, 39 So.Cal.L.Rev. 1, 4 (1966). The most effective way (and, where complex chemical compositions sold under trade names are involved, often the only practical way) in which this can be done is to identify the copied article by its trademark or trade name. *To prohibit use of a competitor's trademark for the sole purpose of indentifying the competitor's product would bar effective communication of claims of equivalence.* Assuming the equivalence of 'Second Chance' and 'Chanel No. 5,' the public interest would not be served by a rule of law which would preclude sellers of 'Second Chance' from advising consumers of the equivalence and thus effectively deprive consumers of knowledge that an identical product was being offered at one third the price."

(emphasis supplied).

Similarly, in *Societe Comptoir de L'Indus., etc.* v. *Alexander's Department Stores, Inc.*, 299 F.2d 33, 36 (2d

Cir. 1962), the defendant had used plaintiff's trademarks "DIOR" and "CHRISTIAN DIOR" in promoting their copies of original fashion designs by the plaintiff. Relief was sought under Section 43(a) of the Lahnam Act. The court stated succinctly that:

> "The Lanham Act does not prohibit a commercial rival's truthfully denominating his goods a copy of a design in the public domain, though he uses the name of the designer to do so."

Finally, in *Saxony Products, Inc.* v. *Guerlain, Inc.*, 513 F.2d 716 (9th Cir. 1975), the court held that a manufacturer of perfume could advertise that its product was similar to Guerlain's "SHALIMAR" product even though "SHALIMAR" was a registered trademark. The court explained that there could be no violation of §43(a) merely through the use of a competitor's trademark, provided that the representations made were accurate and that there was no likelihood that consumers would be confused as to the source of origin of the respective products.

The promotional practices characterized by the Court of Appeals as suggesting and encouraging trademark infringement by retail pharmacists thus were wholly proper and can neither be enjoined in themselves nor be treated as supporting a finding that petitioners "suggested, even if only by implication" (*Ives II*, Pet. App. 35a) that pharmacists improperly apply the CYCLOSPASMOL trademark to petitioners' generic products.

In short, in view of the strong public policy enunciated by this Court in *Sears* and *Compco* and in light of other relevant case law on copying the appearance of products and on contributory trademark infringement, petitioners

cannot be held guilty of violating Section 32 of the Lanham Act on the ground of contributing to the infringement of a registered trademark merely by selling products which simulate the unpatented and uncopyrighted appearance of the respondent's products.

POINT II

Copying by the Appellants of the Appearance of the Respondent's Product Cannot Be Enjoined on the Ground that Such Copying Constitutes or Contributes to a Violation of Section 43(a) of the Lanham Act.

Although the Second Circuit in *Ives IV* purported to rest its decision on the ground of contributory trademark infringement by petitioners in violation of Section 32 of the Lanham Act, it analogized petitioners' conduct to activity that was enjoined as passing off or the inducement of passing off in cases such as *Upjohn, Merrell-National, Squibb,* and *Smith Kline, ubi supra.* Furthermore, the three district court and Court of Appeals decisions herein which preceded *Ives IV* extensively discussed the issue of whether the sale by petitioners of their look-alike products constituted a violation of Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), which was the principal claim asserted by respondent in all phases of this litigation below.[12] Petitioner Premo deems it appropriate to briefly address these questions to demonstrate that not only can petitioners not be enjoined from selling look-alike cyclandelate capsules on the grounds that such sales contribute to the infringement of respondent's trademark CYCLOSPASMOL, but they can also not be enjoined on the theory that such sales either induce passing off by pharmacists or constitute passing off

12. *See* Judge Mulligan's comment on this point at Pet. App. 86a, n.1.

in themselves, and hence "false designations of origin" in violation of §43(a).

As the Court of Appeals correctly held in *Ives II*, in order to establish a right to relief under Section 43(a) of the Lanham Act for simulation of the appearance of a product, it must be established that the appearance, in this case the color of respondent's capsules, is nonfunctional and has acquired secondary meaning. The Second Circuit also held that rights to protection from copying under §43(a) do not conflict with, and cannot be barred by, this Court's ruling in *Sears, supra*, and *Compco, supra* (Pet. App. 48a-49a).[13]

13. This Court has never ruled on the question of whether the policy enunciated in *Sears* and *Compco*, that copying of the appearance of an article of manufacture can be restricted only in accordance with the federal patent and copyright laws, can be circumvented by a claim that the appearance of an article is associated by consumers with a particular source and thus the copying thereof constitutes a false designation of origin or other false representation within the meaning of Section 43(a) of the Lanham Act. It is respectfully submitted that the use of §43(a) to preclude the copying of the unpatented and uncopyrighted appearances of products eviscerates the holding in *Sears* and *Compco*, although that holding is ostensibly directed only at *state* unfair competition laws. Under *Sears*, a party cannot complain of the simulation of its product by a competitor on the grounds of common law unfair competition (or unfair competition under a state statute). But according to the Second Circuit's view, a plaintiff need only allege that its product and its competitor's product are sold in interstate commerce to convert the very same act which cannot be enjoined under state law because of *Sears* into one interdictable under §43(a). Since few companies of any size sell their products solely in intra-state commerce, this interpretation of §43(a) defeats the basic policy of the *Sears* and *Compco* decisions.

Petitioner Premo suggests that even in a case where there is substantial evidence that the mere simulation of the appearance of an article is tantamount to a "false designation of origin" or "false representation in commerce" within the meaning of §43(a), relief under that section should be limited to compelling the imitator to use labeling and advertising to clearly indicate the source of its product to the public, and, in appropriate cases, to affirmatively disassociate its product from the competitor. In addition, the imitator could certainly be enjoined from any practices tending to foster confusion of the public as to source. But no blanket injunction against the copying of appearance should be issued under §43(a) or any other provision of the Lanham Act.

Relief under § 43(a) was denied to the respondent at all stages of this litigation prior to *Ives IV* because, *inter alia*, respondent had not established that the colors of its capsules had acquired a secondary meaning identifying the products' source and that consumers were moved to purchase the products because of that source (*Ives I*, Pet. App. 23a-34a; *Ives II*, Pet. App. 51a; *Ives III*, Pet. App. 64a-69a). This finding that no secondary meaning had been established by the respondent in the colors of its products was not disturbed by the Court of Appeals in *Ives IV* and thus must be accepted as controlling at this stage.

Similarly, it was held in the earlier decisions below that respondent did not establish a right to relief under the New York law of unfair competition (*Ives I*, Pet. App. 25a-27a; *Ives II*, Pet. App. 51a-52a; *Ives III*, Pet. App. 69a-70a) and that ruling was not disturbed by the Court of Appeals in *Ives IV*.

Because the appearance of the respondent's product has not acquired secondary meaning and thus does not serve to identify the source of the product, the sale by petitioners of generic products cannot be said to constitute passing off in itself. Moreover, petitioners affirmatively avoid any possibility that their customers could be deceived as to the source of petitioners' products by clearly labeling bottles of their products so that their customers make no mistake as to the origin of these goods. Nevertheless, the Second Circuit in *Ives IV*, in its discussion of the alleged §32 violation, at least impliedly characterized petitioners' sales practices as enjoinable because the sale of look-alike prescription drug products induces passing off by pharmacists

(aside from contributing to the pharmacists' infringement of respondent's registered trademark by the use of the same on the prescription bottles). In other words, one can infer that the *Ives IV* Court was of the opinion that the mere sale of these look-alike capsules was likely to confuse consumers accustomed to the appearance of the brand name product, whether or not the CYCLOSPASMOL trademark was applied to the prescription bottles by pharmacists.

Any contention that copying of the uncopyrighted and unpatented appearance of respondent's drug products could be enjoined on the ground that such copying encouraged, induced, or suggested to purchasers that they pass off these products on unwitting customers runs afoul of the policy of free competition set forth in *Sears* and *Compco* (and discussed previously[14]) to at least as great a degree as the assertion that such copying could be enjoined because it contributes to infringement of a registered trademark. Even before the *Sears* and *Compco* decisions, however, courts faced with situations where the appearance of prescription drug products had been copied and passing off at the retail level had allegedly occurred did not issue injunctions against the copying of the unprotectable appearance of the product but instead sought to restrain the ancillary predatory or unfair competitive practices which were directly responsible for encouraging passing off.

In *William R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526 (1924), a case dealing, like the present one, with the color of a drug product, this Court held that plaintiff Lilly had no right to stop the defendant from selling a product looking exactly like Lilly's. Although the Court disap-

14. See pp. 8-11, *supra*.

proved of the suggestions made by the defendant's salesmen that the defendant's products could be substituted for Lilly's without danger of detection on prescriptions and on orders for the Lilly product, and the Court further condemned the defendant's pointing out to druggists the identity of the two preparations and the enhanced profits to be made by selling the defendant's product because of its lower price, the Court would not grant an injunction against the sale of the look-alike drug product but instead limited its relief to interdicting the predatory and unfair competitive practices of the defendant which were inducing illegal substitution and passing off.

The *Ives II* opinion contains an excellent discussion of the *Warner* case as well as several other cases involving copying of the appearance of drug products wherein the courts refused to enjoin the copying itself but instead directed their injunctive relief against the express palming off of the accused products or practices such as direct inducement of substitution and passing off by the defendants or their agents (Pet. App. 36a-42a). These cases include *Smith Kline & French Laboratories* v. *Clark & Clark*, 157 F.2d 725 (3d Cir. 1946), *cert. denied*, 329 U.S. 796 (1946) (actual palming off enjoined and defendants required to stamp their tablets with a distinguishing mark); *Norwich Pharmacal Co.* v. *Sterling Drug, Inc.*, 271 F.2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960) (court refused to enjoin copying of the color of plaintiff's medication because there was no proof of secondary meaning, palming off, actual deception or appropriation of another's property); and *Upjohn Co.* v. *Schwartz*, *supra*.

If petitioners were guilty of ancillary unfair competitive practices, as were the defendants in cases such as

Warner, supra, and *Upjohn, supra,* an injunction might perhaps lie against those specific practices, but under no circumstances could petitioners be enjoined from copying the respondent's capsule colors on the facts of the present case.

With respect to the requirement for a valid cause of action under §43(a) that the appearance of the product, the imitation of which is sought to be enjoined, must be non-functional, the district court clearly found that the colors of petitioners' products are functional in several respects (*Ives III,* Pet. App. 63a-64a).

The trial court based its finding of functionality on the evidence put in by petitioners which demonstrated the following: First, many elderly patients associate the appearance of their medication with its therapeutic effects and, once they have become accustomed to the brand name drugs' appearance, they will be reluctant and may be caused anxiety when asked to accept a generic equivalent in an unfamiliar appearance. Second, many patients (in particular the elderly, who are the main consumers of cyclandelate) co-mingle their drugs of different types in a single container and then rely on the appearance of each drug to follow their doctors' instructions. It is, therefore, important that a brand name drug and its generic therapeutic equivalents have a uniform appearance so that doctors can use the appearance of the drug in communicating instructions to patients regarding their medications. Third, to a limited extent, color is useful to doctors and hospital emergency rooms in identifying drugs in overdose cases. The color of the capsule frequently provides a clue in the difficult and hurried effort to determine what a patient has ingested (Pet. App. 63a).

There was further evidence in the record below that one of the petitioners (Inwood Laboratories) had attempted to sell a generic cyclandelate product in a color totally dissimilar to respondent's products, and the non-look-alike product was not accepted by hospitals, pharmacies and wholesalers (Pet. App. 63a-64a). This failed attempt to sell a generic cyclandelante product with an appearance different from respondent's CYCLOSPASMOL sharply illustrates the commercial functionality of the appearance of respondent's products.

The Court of Appeals rejected petitioners' arguments as to the legitimate reasons for their copying of the functional appearance of respondent's products as "unconvincing" (Pet. App. 85a). Judge Mulligan, however, in his dissent, properly criticized the majority's contention that no persuasive evidence of a legitimate reason for using the appearance of respondent's product was offered by petitioners (Pet. App. 90a-91a). He observed that the majority did not characterize the trial court's findings on the question of functionality and on petitioner's motivations in copying the CYCLOSPASMOL appearance as "clearly erroneous", but, instead, ignored the evidence on which the trial court relied in these respects and its findings of credibility with regard to the testimony of witnesses who appeared before it.

Petitioners respectfully submit that the trial court's findings on the question of functionality should be regarded as authoritative and that petitioners can therefore not be enjoined from the sale of their look-alike generic cyclandelate products under §43(a) because that appearance has not been proven to be non-functional; and because, as discussed previously, respondent never established that that appearance had acquired secondary meaning.

POINT III

Even if the Appearance of Respondent's Blue Capsules Were Associated by the Public with Respondent, Petitioners Could Not Be Enjoined from Copying that Appearance Because the Public Recognition Thereof Was Acquired During the Period of Respondent's Patent Monopoly.

Until April 26, 1972 respondent owned a patent which covered the drug cyclandelate and was the only manufacturer that had ever marketed that drug in the United States (Pet. App. 56a; 75a). Respondent began to use the pale blue color of one of its CYCLOSPASMOL products (the 200 mg. capsule), which was copied by petitioners and which is at issue in this case, during the term of the patent (Pet. App. 57a). Because cyclandelate capsules originated with respondent and no other manufacturer during the term of the patent, it is logical to assume that consumers may have associated the pale blue color of the product with a capsule containing CYCLOSPASMOL brand cyclandelate, *solely because those were the only cyclandelate capsules available on the market and prescribed to patients.* Thus, even if respondent had been able to establish at trial that the appearance of its 200 mg. product was associated by the public with CYCLOSPASMOL brand cyclandelate, the holding of this Court in *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111 (1938) would bar the granting of relief to respondent against the copying of that appearance.

In *Kellogg*, the plaintiff, National Biscuit Co., had at one time owned a design patent on the pillow shape of its shredded wheat product. Upon expiration of the patent,

the defendant made shredded wheat in the pillow shape and was charged with unfair competition. The Supreme Court reversed the lower court decision granting relief, stating as follows:

> "The plaintiff has not the exclusive right to sell shredded wheat in the form of a pillow-shaped biscuit —*the form in which the article became known to the public.*
>
> • • •
>
> "Where an article may be manufactured by all, a particular manufacturer can no more assert exclusive rights in a form in which the public has become accustomed to see the article and which, in the minds of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind."

305 U.S. at 119-20 (emphasis supplied).

The rationale of the *Kellogg* case applies with full force to the case at bar. The respondent herein should no more be permitted to secure protection for the blue color of its 200 mg. CYCLOSPASMOL capsules than it could for the generic name of the product, i.e., cyclandelate. Like the pillow-shaped appearance of National Biscuit Co.'s shredded wheat, the color of respondent's capsules developed any significance they may have to consumers during the period when respondent held a legal monopoly in the cyclandelate market under its patent. Granting an injunction against copying the appearance of respondent's capsules controverts the principle expressed by this Court in *Kellogg* as follows:

> "Sharing in the goodwill of an article unprotected by patent or trademark is the exercise of a right pos-

sessed by all—and in the free exercise of which the consuming public is deeply interested."

Kellogg, supra at 122, quoted in *Sears, Roebuck & Co.* v. *Stiffel Co., supra* at 231.

POINT IV

Copying of the Appearance of Respondent's Products by Petitioners Cannot Be Enjoined on the Basis of Illegal Acts Committed by a Small Number of Licensed Professionals Who Utilize Those Products.

In reversing the district court's finding in *Ives III* that insufficient evidence had been introduced by respondent at trial to establish a violation of Section 32 of the Lanham Act, the Second Circuit in *Ives IV* relied on certain shopping surveys that were conducted by respondent which allegedly showed that a significant number of retail pharmacists infringed the registered trademark CYCLOSPASMOL by mislabeling petitioners' generic products with that trademark (Pet. App. 81a-82a).

In fact, as argued by Judge Mulligan in dissent (Pet. App. 88a), only 10 out of 83 pharmacies shopped were found to have committed any improper acts. Moreover, 9 out of the 10 druggists involved obviously had no intention of passing off the generic products as the brand name drug as evidenced by the fact that they specifically advised the patient purchasing the drug *that they were receiving a generic product* (*id.*). In addition, 5 out of the 10 druggists who used the word "CYCLOSPASMOL" on the prescription vial label also included the word "generic" or its abbreviation before or after the respondent's trademark, in-

dicating their desire to convey to the patient that a generic version of respondent's CYCLOSPASMOL product was being dispensed (*id.*). Only one pharmacist actually passed off a generic cyclandelate product as respondent's CYCLOSPASMOL when the prescription presented did not permit substitution of a generic, and only that pharmacist charged the higher brand name price for the generic and thus reaped any profit from his improper actions (*id.*).

The Second Circuit relied on this rather meager showing of instances where the respondent's CYCLOSPASMOL trademark was infringed by pharmacists selling petitioners' generic products in ruling that petitioners should be enjoined from copying the appearance of CYCLOSPASMOL. There was not even any evidence that the trademark infringement by the pharmacists was in any way related or tied to the fact that these generics had the same appearance as CYCLOSPASMOL. It is far more likely that at least the nine pharmacists who informed the patients that they were receiving a generic mislabeled the product as CYCLOSPASMOL or "CYCLOSPASMOL generic" because they were unaware of the correct generic name or because of a misunderstanding of the law, and that same ignorance or misunderstanding would have prevailed no matter what colors petitioners' generic products were sold in.

In any case, this Court has held that unscrupulous or improper acts committed by individual professional practitioners such as pharmacists and lawyers do not provide a basis for a blanket prohibition against practices that are essentially in the public interest. See *Bates* v. *State Board of Arizona*, 433 U.S. 350 (1977); *Virginia State Board of*

Pharmacy v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

There was evidence in this case in the form of testimony by one of respondent's own witnesses, the President of the New York State Pharmaceutical Society, that he personally knew of no illegal substitution of generic for brand name drugs and that he did not believe the practice was widespread (Pet. App. 69a; 89a, n.2). Furthermore, there was never any doubt that pharmacists who committed illicit acts such as illegal substitution or passing off of a generic drug as a brand name drug are subject to civil and criminal penalities.[15] (Pet. App. 69a).

The Second Circuit held that the fact that a few pharmacists committed these violations of state law and of their professional duty, either deliberately or out of ignorance, provided sufficient ground for enjoining petitioners from copying the appearance of respondent's CYCLOSPASMOL on the unsupported assumption that these unethical or misinformed pharmacists would be deterred from their acts if generic cyclandelate products were sold only with appearances distinguishable from CYCLASPASMOL.

It is respectfully submitted that the entire approach of the Court of Appeals to the question of how best to remedy individual instances of illegal substitution or mislabeling

15. The majority in *Ives IV* relied on the existence of six indictments in New York of pharmacists who allegedly illegally substituted and mislabeled generic cyclandelate for CYCLOSPASMOL as evidence that the practice was becoming widespread (Pet. App. 83a-84a). In fact, as Judge Mulligan noted in dissent (Pet. App. 90a), such indictments, while not proof of any illegality and not evidence of widespread illegal practices, would, if anything, help discourage other unethical pharmacists from committing similar acts.

by retail pharmacists, i.e., by enjoining the sale of look-alike cyclandelate products to all pharmacists anywhere in the country, runs counter to the approach adopted by this Court in the *Bates* and *Virginia Pharmacy* cases, *supra*, and is not at all in the public interest.

Substantial evidence was put in by petitioners at trial to establish that the sales of generic drugs with an appearance that simulates the branded drugs to which they are equivalent serves important utilitarian purposes and makes the generic products more acceptable, in particular to elderly consumers who are the main purchasers of a drug such as cyclandelate and who can least afford the higher-priced brand name drugs (see pages 25-26, *supra*). In *Ives II*, the Second Circuit itself commented that the district judge was warranted in finding some merit to petitioners' arguments that their copying of the CYCLOSPASMOL colors for their generic products was motivated by important policy considerations (Pet. App. 50a). In *Ives IV*, however, the Court of Appeals merely brushed aside the trial court's detailed findings of fact with regard to petitioners' legitimate motivations for copying and held that petitioners sold look-alike cyclandelate products only because they anticipated that such products would be acceptable to a substantial number of druggists who intended to substitute the product illegally for, or mislabel it as, CYCLOSPASMOL capsules.

The net effect of the Second Circuit decision is to preclude the public from purchasing therapeutically equivalent, lower-priced generic substitutes for CYCLOSPASMOL in the appearance to which the public has become accustomed *even when pharmacists properly dispense those*

drugs, i.e., without use of the respondent's trademark, as is true in the great majority of cases even according to the record established in this case. The Court of Appeals disregarded all applicable precedents which stress that copying of the unpatented, uncopyrighted appearance of a product cannot be enjoined even when unfair practices are committed therewith by purchasers, and also ignored this Court's holdings in the *Bates* and *Virginia Pharmacy* cases, *supra*, against the blanket suppression of commercial practices legitimate in themselves on the ground that some licensed professionals may commit improper acts by perverting or abusing those practices.[16]

Clearly, any remedy against illegal substitution or passing off by certain pharmacists should be directed against those pharmacists. At most, petitioners should be required only to provide clear warnings on their products that they are not to be sold or dispensed except in accordance with state drug substitution laws and are not to be mislabeled as respondent's CYCLOSPASMOL capsules. No further relief is justified by the facts in this case or by the applicable law.

16. Obviously, the Second Circuit in *Ives IV* believed that the practice of copying the appearance of a drug should be made unlawful. Confronted by the district court's findings, which it could not reverse as clearly erroneous, the Court of Appeals found a way to prevent the copying by resorting to Section 32 of the Lanham Act.

Conclusion

The judgment of the United States Court of Appeals for the Second Circuit appealed from herein should be reversed.

Respectfully submitted,

PETER T. COBRIN
KIRSCHSTEIN, KIRSCHSTEIN,
OTTINGER & COBRIN, P.C.
Attorneys for Petitioner
Premo Pharmaceutical Laboratories, Inc.
666 Fifth Avenue
New York,New York 10103
(212) 581-8770

Of Counsel:
DAVID B. KIRSCHSTEIN
MARTIN W. SCHIFFMILLER